

### Remarks

The applicants have canceled claim 1 and re-written it in product-by-process form in new claim 17. The applicants have also amended claim 9 to conform to the language of new claim 17.

#### **Rejection claims 1-4 under 35 U.S.C. § 102(e)**

Claims 1-4 were rejected as anticipated by LaPosta. The applicants respectfully submit that the presently claimed compositions do not encompass the compositions of LaPosta because LaPosta does not store a liquid composition comprising trehalose and an antigen. Rather, LaPosta works under the presumption that lyophilization is necessary for long term storage of a vaccine composition and is concerned with improving the properties of monophosphoryl lipid A as an adjuvant when subjected to lyophilization. Accordingly, LaPosta teaches lyophilizing its composition for storage. LaPosta does not teach storing a liquid vaccine composition. Because (among other reasons) a liquid vaccine composition will inherently undergo changes over time (although some of those changes are attenuated by trehalose), the presently claimed liquid vaccine compositions are different from those of LaPosta. Hence, LaPosta cannot anticipate the present claims.

#### **Rejection of claims 1-8 and 11-16 under 35 U.S.C. § 103**

Claims 1-8 and 11-16 were rejected as obvious over Anderson in view of Roser. The applicants respectfully traverse.

Roser is directed to preventing aggregation in protein compositions that are frozen and thawed (or lyophilized and reconstituted) to maintain the activity of the protein. The stability over time that Roser teaches is protein activity in a solid composition (i.e., protein aggregation is prevented and activity maintained after the solid is stored). Roser does not consider and, hence, does not reasonably suggest maintenance of immunogenicity in a liquid composition stored over time.

Furthermore, one of ordinary skill in the art would not be able to predict from Roser's teachings that a protein-polysaccharide conjugate in a liquid composition comprising trehalose would maintain its immunogenicity for extended periods of time (e.g., 6-months, as in Example 3 of the present specification). This property is unexpected, rendering the claims non-obvious.

Anderson provides no teachings to compensate for the deficiencies of Roser.

**Rejection of claims 9-13 and 16 under 35 U.S.C. § 103**


Claims 9-13 and 16 were rejected as obvious over Roser in view of LaPosta. For the following reasons the applicants respectfully traverse.

As described above, both Roser and LaPosta are directed to methods of improving vaccine compositions that are subject to freezing/thawing and/or lyophilization/reconstitution. Neither Roser nor LaPosta suggest a vaccine composition that has been stored in the liquid state. Rather, the underlying presumption of both Roser and LaPosta is that the vaccine compositions that are the subject of their respective disclosures are stored in the solid state. They provide no teaching or suggestion to store in the liquid state a vaccine composition such as presently claimed. Nor do they provide any teachings from which the ordinary artisan could reasonably expect that a liquid vaccine composition such as presently claimed would maintain its immunogenicity.

In view of the foregoing, the applicants respectfully request reconsideration and withdrawal of the pending § 102 and § 103 rejections. If there are any questions or comments regarding this response or application, the Examiner is encouraged to contact the undersigned attorney as indicated below.

Respectfully submitted,

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